

Attorney Docket No.: DRE-0055
Inventors: Laurencin et al.
Serial No.: 09/878,641
Filing Date: June 11, 2001
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REMARKS

Claims 1-12 are pending in the instant application.

The amendment filed by Applicants August 4, 2006 was not entered. In the Advisory Action mailed August 18, 2006, the Examiner indicated that the proposed amendment was more properly directed to method steps.

Accordingly, in an earnest effort to clarify the status of the pending claims, Applicants are providing herewith a listing of the pending claims prior to submission of the August 4, 2006 amendment. Since this amendment was not entered by the Examiner, Applicants believe that the claims as presented herein are the claims currently under examination.

The rejection of claims 1-12 under 35 U.S.C. 103(a) has been maintained. Reconsideration is respectfully requested in light of the following remarks and evidence submitted herewith via an Inventor Declaration.

Claims 1-3, 6-9 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wolowacz et al. (WO 95/01810 A1) in view of Chervitz (U.S. Patent 4,917,699).

Claims 4, 5, 10 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wolowacz et al. in view of Chervitz as applied to claims 2 and 8, and further in view of Vacanti (U.S. Patent 5,855,610).

Applicants respectfully traverse these rejections.

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Arguments previously presented by Applicants regarding the unexpected superiority of the three-dimensional braided scaffolds of the instant invention were deemed unpersuasive because the comparison was made to a microfibrer, non-woven mesh scaffold prepared from the same biodegradable materials, not a two-dimensional braided scaffold such as disclosed by Wolowacz et al.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are providing herewith a Declaration by inventor Cato T. Laurencin describing in detail the advantages of the three-dimensional braided scaffolds of the instant invention over two-dimensional braided scaffolds. In particular, in paragraph 3 of Dr. Laurencin's Declaration, he discusses disadvantages of commercially available two-dimensional braided scaffolds which inhibit collagen filtration to a few layers leading to a loss in structural integrity, surface peeling, axial splitting of fibers and stability issues with side-to-side placement. In paragraph 4 of Dr. Laurencin's Declaration, he discusses the superior properties of the three-dimensional braided scaffolds of the present invention as compared to the products discussed in paragraph 3 of his Declaration. In particular, Dr. Laurencin states that the 3-D braided structures overcome some of the problems of poor tissue integration, poor abrasion resistance and fatigue

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failure through the development of an interconnected network of porous structure that will help the transportation of oxygen and nutrients throughout the implant site. See paragraph 4 of Dr. Laurencin's Declaration.

Further, in paragraph 5 of Dr. Laurencin's Declaration, he describes results from experiments comparing cell ingrowth in 3-D braided scaffolds and 2-D braided scaffolds of the same material. Experiments were performed with 4 different cell types. See paragraph 5 and Figures 1 and 2 of Dr. Laurencin's Declaration. In these experiments, cell ingrowth was at least 3-fold to almost 100-fold higher in the 3-dimensional braided scaffolds of the present invention as compared to 2-dimensional braided scaffolds of the same material. See Table 1 of Dr. Laurencin's Declaration.

The experiments presented in Dr. Laurencin's Declaration clearly demonstrate an unexpected superior property of the three-dimensional braided scaffolds of present invention over two-dimensional braided scaffolds such as those of Wolowacz. Accordingly, the evidence presented in Dr. Laurencin's Declaration, in particular the experiments described in paragraph 5, overcomes any prima facie case of obviousness over the cited combinations of prior art references.

Withdrawal of these rejections under 35 U.S.C. § 103(a) is therefore respectfully requested.

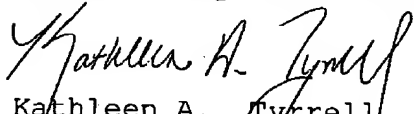
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Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Actions of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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